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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 15, 2003, from 8 a.m. to 4:30 p.m.

Location: Center for Drug Evaluation and Research (CDER) Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Thomas H. Perez, CDER (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–6758, e-mail: *PerezT@cder.fda.gov*, or the FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting. Background materials for this

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meeting, when available, will be posted on FDA's Web site 1-business day before the meeting at *www.fda.gov/ohrms/dockets/ac/acmenu.htm*.

Agenda: The subcommittee will discuss the following topics: (1) Pharmacogenetic testing for thiopurine methyltransferase deficiency in patients for whom treatment with 6-mercaptopurine is being considered; and (2) overcoming challenges in pediatric oncology product development: regulatory oversight of multinational clinical studies.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by July 7, 2003. Oral presentations from the public will be scheduled between approximately 10 a.m. and 10:30 a.m. and 1 p.m. and 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 7, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please notify Thomas Perez at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: 6/23/03
June 23, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

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